UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No.: 0:22-cv-61192-WPD

SCILEX PHARMACEUTICALS INC., ITOCHU CHEMICAL FRONTIER CORPORATION, AND OISHI KOSEIDO CO., LTD.,

Plaintiffs,

v.

AVEVA DRUG DELIVERY SYSTEMS, INC., APOTEX CORP., AND APOTEX INC.,

Defendants.

JOINT SCHEDULING REPORT AND PROPOSED CASE MAGEMENT PLAN

Pursuant to Federal Rule of Civil Procedure 26(f), Local Rule 16.1, and this Court's Order Requiring Counsel to Meet, File Joint Scheduling Report and Joint Discovery Report (D.I. 6), Plaintiffs Scilex Pharmaceuticals Inc., ITOCHU CHEMICAL FRONTIER Corporation, and Oishi Koseido Co., Ltd. (collectively "Plaintiffs"), and Aveva Drug Delivery Systems, Inc., ("Aveva") and Apotex Corp. (together "Defendants"[1]) by and through undersigned counsel, respectfully submit this Joint Scheduling Report and Proposed Case Management Plan.[2] On July 29, 2022,

[1]Specially-Appearing named defendant Apotex Inc. filed a motion to dismiss on September 2, 2022 (DE 37) maintaining that Apotex Inc. is not a proper or necessary party; that this Court lacks personal and subject matter jurisdiction; and that the Complaint against Apotex Inc. fails to state a claim for which relief can be granted. Specially-Appearing Apotex Inc. has not participated in the negotiation or preparation of this Scheduling Report or Proposed Case Management Plan. In any event, and even if the pending motion to dismiss were denied, specially-appearing Apotex Inc. would not seek to modify any Joint Scheduling Report and Proposed Case Management Plan agreed to by Plaintiffs and Defendants.

[2]Plaintiffs' Position: Apotex Inc. is a proper and necessary party. Apotex Inc., was served on July 29, 2022 (D.I. 22), is represented by the same counsel as Aveva and Apotex

counsel for the parties conferred telephonically regarding the matters specified in the Court's order and the respective rules. A report of the conference and proposed case schedule and management plan follow.

I. PROPOSED MONTH AND YEAR FOR TRIAL

June, 2024.

II. CASE MANAGEMENT TRACK AND NUMBER OF TRIAL DAYS

The parties propose that this case should be assigned to the complex case management track as set forth in Local Rule 16.1(a)(2)(C). The parties estimate that trial will take approximately 5-10 days.

III. LOCAL RULE 16.1(B)(2) CONFERENCE REPORT

A. Likelihood of Settlement

The parties intend to discuss settlement and will promptly advise the Court if any settlement is reached. At this time, however, the likelihood of settlement is not known.

B. Likelihood of Additional Parties

The parties do not currently anticipate that additional parties will be added to this action.

C. Proposed Limits on Time

The parties respectfully direct the Court to Section V below.

D. Proposal for the Formulation and Simplification of Issues; Number and Timing of Motions for Summary Judgment

The parties will work cooperatively to limit the number of asserted claims and prior art references asserted.

Corp., and has had an opportunity to participate in the negotiation and preparation of this Scheduling Report and Proposed Case Management Plan.

The parties' proposal for the timing of motions for summary judgment or partial summary judgment are respectfully submitted in Section V below.

E. Amendments to the Pleadings

The parties anticipate that any amendments to the pleadings will be made by the deadline set forth in Section V below.

F. Possibility of Obtaining Admissions of Facts and of Documents

The parties will attempt to work cooperatively to minimize evidentiary issues without intervention of the Court.

G. Suggestions for the Avoidance of Unnecessary Proof and of Cumulative Evidence

At this time, the parties have no suggestions for avoiding unnecessary proof. The parties understand that admissions of facts and authenticity of documents will be a means of avoiding unnecessary proof and that stipulations addressing such matters may be appropriate. The parties will attempt to work cooperatively and confer as to ways to avoid unnecessary proof and cumulative evidence.

H. Suggestions on the Advisability of Referring Matters to a Magistrate Judge

The parties agree to have all discovery motions and discovery disputes heard and decided by the Magistrate Judge. The parties reserve the right to object to any Magistrate Judge order pursuant to Fed. R. Civ. P. 72(a). The parties do not consent to a full disposition of the case by the Magistrate Judge and do not consent to a Magistrate judge for the *Markman* hearing, trial, case dispositive motions, or the entry of final judgment.

I. Requested Date or Dates for Conferences Before Trial, a Final Pretrial Conference, and Trial

Please see Section V below.

J. Other Information that Might be Helpful to the Court in Setting the Case for Status or Pretrial Conference

This controversy arises under the Hatch-Waxman Act. FDA approval of Defendants' ANDA Application No. 217221 under 35 U.S.C. § 355(c)(3)(C) is stayed until at least November 11, 2024.

IV. RULE 26(F) CONFERENCE REPORT

A. Nature and Basis of the Claims and Defenses and the Possibility of a Prompt Settlement or Resolution of the Case

This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by defendant Aveva Drug Delivery Systems, Inc. of an Abbreviated New Drug Application ("ANDA") No. 217221 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a Lidocaine Topical System, 1.8% product ("Aveva's ANDA Product"), a generic version of Scilex Pharmaceuticals Inc.'s ZTLIDO® (lidocaine topical system) 1.8% ("ZTlido®"), prior to the expiration of U.S. Patent Nos. 9,283,174, 9,925,264, 9,931,403, 10,765,640, 10,765,749, and 11,278,623. Aveva Drug Delivery Systems, Inc. notified Scilex Pharmaceuticals Inc., ITOCHU CHEMICAL FRONTIER Corporation, and Oishi Koseido Co., Ltd. (collectively "Plaintiffs") that it had submitted this ANDA by a letter dated May 10, 2022. Plaintiffs filed this civil action for infringement of U.S. Patent Nos. 9,283,174, 9,925,264, and 9,931,403 (collectively "the Asserted Patents") on June 22, 2022. (D.I. 1). On July 15, 2022, Aveva filed Counterclaims against Plaintiffs for a declaratory judgment of noninfringement and invalidity for each of the Asserted Patents, and for U.S. Patent Nos. 10,765,640, 10,765,749, and 11,278,623. (D.I. 12). On August 4, 2022, Plaintiffs provided Defendants with a covenant not to sue on the U.S. Patent Nos. 10,765,640, 10,765,749, and 11,278,623. Defendants' unopposed motion to dismiss their declaratory judgement counterclaims

as to U.S. Patent Nos. 10,765,640, 10,765,749, and 11,278,623 without prejudice was granted on August 31, 2022.

Regarding settlement or early resolution, all parties are open to the possibility of settlement, settlement. No settlement is imminent at this time.

B. Changes That Should Be Made in the Timing, Form, or Requirement for Disclosures Under Rule 26(a), Including a Statement of When Initial Disclosures Are to Be Made

The parties shall make their respective Rule 26(a) initial disclosures no later than two weeks after the filing of this Joint Scheduling Report.

C. Subjects On Which Discovery May Be Needed and When Discovery Should Be Completed

Plaintiffs anticipate the need for discovery on the following subjects, including but not limited to the following: ANDA No. 217221; Defendants' preparation and submission of ANDA No. 217221 to the FDA; Defendants' knowledge and pre-suit analysis of the patents-in-suit; Defendants' design, development, testing and analysis of the product that is the subject of ANDA No. 217221; Defendants' design, development, testing and analysis of any other lidocaine patch formulations; and Defendants' testing and analysis of Plaintiffs' ZTlido® product; Defendants' basis for its allegations of non-infringement and invalidity.

Defendants anticipate the need for discovery on the following subjects, including but not limited to: the conception and reduction to practice of the claims of the Patents-in-Suit; Plaintiffs' design, development, testing, manufacturing, and analysis of ZTLido®; Scilex's NDA No. 207962; Scilex's preparation and submission of NDA No. 207962; Plaintiffs' design, development, testing and analysis of any lidocaine patch formulations besides ZTLido®; Plaintiffs' basis for its allegations of infringement; Plaintiffs' contentions regarding the alleged validity of the Patents-in-Suit; prior art related to the Patents-in-Suit; any Plaintiffs' licensing, assignment, or sale of the

Patents-in-suit; Plaintiffs' knowledge of prior art related to the Patents-in-Suit; and the patent prosecution of the Patents-in-Suit.

The parties agree that discovery may be taken upon service of the propounding party's initial disclosure, under Rule 26(a). Discovery will be completed by the date set forth in Section V below.

D. Any Issues About Disclosure, Discovery, or Preservation of Electronically Stored Information, Including the Form or Forms in Which It Should Be Produced

The parties anticipate the need for some electronic discovery and have taken steps to ensure the preservation of relevant documents and electronically stored information ("ESI"). The parties will work diligently to resolve any issues regarding the discovery, disclosure, or preservation of electronically stored information ("ESI") without the need for intervention by the Court. The parties agree that no separate ESI discovery order is required in this case, but agree to the following with respect to production of ESI.

(a) **Format.** ESI and non-ESI shall be produced to the requesting party as text searchable image files (e.g., PDF or TIFF). When a text-searchable image file is produced, the producing party must preserve the integrity of the underlying ESI, i.e., the original formatting, the metadata (as noted below) and, where applicable, the revision history. The parties shall produce their information in the following format: single page TIFF images and associated multi-page text files containing extracted text or OCR with Concordance and Opticon load files containing all requisite information including relevant metadata.

(b) **Native Files.** The only files that should be produced in native format are files not easily converted to image format, such as Excel and Access files.

(c) **Metadata Fields.** The parties are only obligated to provide the following metadata for all ESI produced , to the extent such metadata exists: Custodian, File Path, Email Subject, Conversation Index, From, To, CC, BCC, Date Sent, Time Sent, Date Received, Time Received, Filename, Author, Date Created, Date Modified, MD5 Hash, File Size, File Extension, Control Number Begin, Control Number End, Attachment Range, Attachment Begin, and Attachment End (or the equivalent thereof).

E. Any Issues About the Claims of Privilege or of Protection as Trial-Preparation Materials, Including—If the Parties Agree on a Procedure to Assert These Claims After Production—Whether to Ask the Court to Include Their Agreement In an Order Under Federal Rule of Evidence 502

The parties anticipate submitting a Stipulated Protective Order in this case and will follow the procedures for asserting claims of privilege set forth therein.

F. Changes to Limitations on Discovery

The parties agree to the following limits on discovery[3]:

(a) Discovery Cut Off. All document discovery in this case shall be initiated so that it will be completed on or before the date specified in Section V below.

(b) Document Production. Document Production shall be substantially completed on or before the date specified in Section V below.

(c) Requests for Production of Documents and Things. A maximum of **75** for requests for production of documents and things is permitted for each side.

(d) Requests for Admission. A maximum of **50** requests for admission is permitted for each side. These limitations do not apply to requests for admission directed to the

[3] As used herein the term "side" means Plaintiffs (collectively Scilex Pharmaceuticals Inc., ITOCHU CHEMICAL FRONTIER Corporation, and Oishi Koseido Co., Ltd.) or Defendants (together Aveva and Apotex Corp.).

authentication of documents under Federal Rule of Evidence 901 or the business record exception under Federal Rule of Evidence 803(6), subject to objections to undue burden.

(e) Interrogatories. A maximum of **25** interrogatories is permitted for each side.

(f) Depositions. Each side is limited to a total of **60** hours of taking fact testimony by deposition upon oral examination. Fact depositions are limited to **7** hours on the record, except depositions of witness requiring translation will last no more than **10** hours on the record, and must be completed in one day. Every hour of translated testimony shall only count for one half hour of full testimony. For clarity, Rule 30(b)(6) depositions shall count against these limits, but expert depositions shall not count against these limits on fact depositions. Any foreign witness who may be called by the producing party at trial will be made available for deposition in the United States.

G. Claim Construction Procedures

On or before the date specified in Section V below, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction(s) of those term(s)/phrase(s). This document will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be filed on or before the date specified in Section V below. The parties' Joint Claim Construction Chart shall identify for the Court the term(s)/phrase(s) of the claim(s) in issue and should include each party's proposed construction(s) of the disputed claim language with citation(s) to the intrinsic evidence in support of their respective proposed constructions.

Each party shall file their opening brief, not to exceed 25 pages, on or before the date specified in Section V below. Each party shall file their answering brief, not to exceed 15 pages, on or before the date specified in Section V below.

H. Other Orders Under Rule 26(c) or Under Rule 16(b)

The parties anticipate requesting that the Court enter a stipulated protective order to govern the treatment of confidential and trade secret information that may be exchanged during this case.

V. PROPOSED DISCOVERY AND PRETRIAL PLAN

The parties respectfully request that the Court adopt the following schedule, including relevant pleading, discovery, motion and trial deadlines.

Event	Date
Fed. R. Civ. P. 26(a)(1) Disclosures	Within 14 days of this Order
Proposed Protective Order	Within 14 days of this Order
ANDA Production	Within one week of submitting the Protective Order
Parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction(s) of those term(s)/phrase(s)	Dec. 9, 2022
Joint Claim Construction Chart Identifying Intrinsic Evidence	Dec. 16, 2022
Substantial Completion of Document Production	February 3, 2023
Opening Claim Construction Brief	Jan. 20, 2023
Answering Claim Construction Brief	Feb. 17, 2023
Claim Construction Hearing	Apr. 28, 2023 (subject to Court's availability)
Close of Fact Discovery	May 5, 2023
Joinder of Other Parties and Amendment of Pleadings	May 26, 2023
Opening Expert Reports for Issues on which a Party bears the burden of proof	June 16, 2023
Rebuttal Expert Reports	July 28, 2023
Reply Expert Reports	Aug. 23, 2023
Close of Expert Discovery	Oct.14, 2023
Case Dispositive Motions and *Daubert* Motions	Nov. 17, 2023
Opposition Briefs to Case Dispositive Motions and *Daubert* Motions	Dec. 20, 2023
Reply Briefs in Support of Case Dispositive Motions and *Daubert* Motions	Jan. 29, 2024

Event	Date
Pretrial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(3)	At least 30 days before trial
Meeting of Counsel pursuant to Local Rule 16.1(d)	At least 14 days before pretrial conference
Pretrial Stipulation pursuant to local rule 16.1(e)	7 days before pretrial conference
Pre-trial Conference and any *Daubert* hearing(s)	May __, 2024 (subject to Court's availability)
Five to Ten Day Bench Trial	June __, 2024 (subject to Court's availability)
Expiration of 30-month Stay	November 11, 2024

Dated: September 13, 2022

/s/ Robert Visca (with permission)
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